MAY 1 0 2001

K010696

Summary of Safety & Effectiveness
Beckman Coulter™ DNAse B Calibrator

1.0 **Submitted By:**

Richard T. Ross, RAC
Staff Regulatory Specialist, Regulatory Affairs
Beckman Coulter, Inc.
200 South Kraemer Blvd., W-104
Brea, California 92822-8000
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2.0 **Date Submitted:**

March 7, 2001

3.0 **Device Name(s):**

3.1 **Proprietary Names**

Beckman Coulter™ DNAse B Calibrator

3.2 **Classification Name**

Calibrator (21 CFR §862.1150)

4.0 **Predicate Device(s):**

Beckman Coulter Product	Predicate	Manufacturer	Docket Number
Beckman Coulter™ DNAse B Calibrator	SYNCHRON LX® Systems PAB Calibrator	Beckman Coulter, Inc.	K994168

5.0 **Description:**

The Beckman Coulter DNAse B Calibrator is a ready-to-use human serum based liquid calibrator manufactured for Beckman Coulter. Each kit contains 4 X 1 mL bottles of Calibrator.

6.0 **Intended Use:**

DNAse B Calibrator, when used in conjunction with Beckman Coulter reagents, is intended for use on the IMMAGE® Immunochemistry Systems for the calibration of Anti-deoxyribonuclease B [DNB].

7.0 **Comparison to Predicate(s):**

The following tables show similarities and differences between the predicate identified in Section 4.0 of this summary.

Similarities to the Predicate

Reagent	Aspect/Characteristic	Comments
Beckman Coulter DNAse B Calibrator	Source Material: Fresh frozen human plasma that has been defibrinated and processed.	Same as SYNCHRON LX® Systems PAB (Prealbumin) Calibrator
	Storage Temperature (+2°C to +8°C)	
	Liquid, ready-to-use form	
	1 Level of Analyte	

Differences from the Predicate

Reagent	Aspect/Characteristic	Comments
Beckman Coulter DNAse B Calibrator	Intended Use:	DNAse B Calibrator, when used in conjunction with Beckman Coulter reagents, is intended for use on the IMMAGE® Immunochemistry Systems for the calibration of Anti-deoxyribonuclease B [DNB]. PAB Calibrator, when used in conjunction with SYNCHRON Systems PAB reagent, is intended for use on the SYNCHRON LX Systems for the calibration of Prealbumin.

8.0 **Summary of Performance Data:**

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to products already in commercial distribution. Stress stability studies of the DNAse B Calibrator support the Beckman Coulter stability claim of 18 months.

This summary of safety and effectiveness is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and the implementing regulation 21 CFR 807.92.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 1 0 2001

Mr. Richard T. Ross, RAC
Staff Regulatory Specialist, Regulatory Affairs
Beckman Coulter, Inc.
200 South Kraemer Boulevard, W-104
Brea, California 92822-8000

Re: K010696
Trade Name: Beckman Coulter™ DNAse B Calibrator
Regulation Number: 21 CFR§ 862.1150
Regulatory Class: II
Product Code: JIS
Dated: March 7, 2001
Received: March 8, 2001

Dear Mr. Ross:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): ~~Not yet assigned~~ K010696

Device Name:
Beckman Coulter™ DNAse B Calibrator

Indications for Use:
Beckman Coulter™ DNAse B Calibrator, when used in conjunction with Beckman Coulter reagents, is intended for use on the IMMAGE® Immunochemistry Systems for the calibration of Anti-deoxyribonuclease B [DNB].

Clinical Significance:
A calibrator is a device intended for medical purposes for use in a test system to establish points of reference that are used in the determination of values in the measurement of substances in human specimens.

Calibrator (21 CFR §862.1150)

Classification. **Class I I.**

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(per 21 CFR 801.109) Optional Format 1-2-96